

K963467  
JAN. 3, 1997

**DeRoyal Industries, Inc.  
Roll Belt**

**510(k) Summary**

**SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION  
UPON WHICH  
AN EQUIVALENCE DETERMINATION COULD BE BASED**

**SUBMITTER INFORMATION**

**NAME:** DeRoyal Industries, Inc.  
**ADDRESS:** 200 DeBusk Lane  
Powell, TN 37849

**TELEPHONE:** (423) 938-7828  
**CONTACT:** Camille Matlock  
**DATE OF PREPARATION:** August 30, 1996

**DEVICE NAMES**

**NAME:** DeRoyal Industries, Inc. Roll Belt  
**COMMON/USUAL NAME:** Roll Belt  
**CLASSIFICATION NAME (if known):** Restraint, Protective (80FMQ)

**PREDICATE OR LEGALLY MARKETING DEVICES**

J.T. Posey Company  
DeRoyal Industries, Inc.

**DEVICE DESCRIPTION**

The DeRoyal Industries, Inc. Roll Belt is a protective restraint device that is intended for medical purposes to limit patient movements so that the patient remains in the bed while allowing the patient to move from side to side thereby enabling examination or protection of the patient or others.

Device Design/Materials Used/Physical Properties: The DeRoyal Roll Belt is designed similar to those marketed by other manufacturers. The Roll Belt is primarily comprised of nylon or polyester seat belt webbing and cotton flannel.

**DEVICE INTENDED USE**

The DeRoyal Industries, Inc. Roll Belt is indicated for use, at the discretion of a responsible licensed healthcare professional, to limit patient movements thereby enabling examination or protection of the patient or others. The DeRoyal Industries, Inc. Roll Belt is intended to be used with a bed.

**TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETING DEVICE(S)**

Characteristic	DeRoyal Device	Other Devices
Materials	Primarily comprised of nylon or polyester seat belt webbing. Materials also include cotton flannel and foam rubber for soft padding. Fasteners are either a hook and loop or a buckle.	Same
Size	Small, Medium, and Large	Same
Vehicles for Attachment	Bed	Same
Length of use	Doctor must prescribe every 24 hours	Same
Level of Patient Activity	Mildly Agitated or disoriented	Same

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